DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

July 25, 2002

VIA FEDERAL EXPRESS—Next Day

Mr. Milton Beard, Owner
Blackjack Ridge Dairy
7500 Gordon Lawrence Road
Santa Fe, TN 38482

Warning Letter No. 02-NSV-31

Dear Mr. Beard:

An inspection of your dairy farm located in Santa Fe, Tennessee, was conducted by our investigator on May 29, 2002. That inspection confirmed that you offered cows for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act. You can find this Act and associated regulations through links on FDA's home page at www.fda.gov.

On or about March 14, 2002, you sold a cow identified by U.S. Department of Agriculture (USDA) sample number 445352 and back tag number 0939 to [redacted], which was then slaughtered for human food at [redacted]. USDA analysis of tissue samples collected from that cow identified the presence of 0.06 parts per million (ppm) penicillin in kidney tissue and 5.95 ppm, 1.12 ppm, and 16.9 ppm tilmicosin in liver, muscle and kidney tissue, respectively. A tolerance of 0.05 ppm has been established for residues of penicillin in edible tissue of cattle (Title 21, Code of Federal Regulations (CFR) Section 556.510). A tolerance of 1.2 ppm in liver tissue has been established for residues of tilmicosin in target tissue of cattle (Title 21 CFR Section 556.735). There are no established tolerances for tilmicosin in kidney and muscle tissues in target tissue of cattle. In 21 CFR Section 558.618, tilmicosin is limited for use in swine feed only. The presence of these drugs in the edible tissues from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about March 14, 2002, you also sold a cow identified by USDA sample number 445351 and back tag number 0940 to [redacted] which was slaughtered for human food at [redacted]. USDA analysis of tissue samples collected from that cow identified the presence of 0.19 ppm penicillin in kidney tissue; 2.68 ppm, 1.39 ppm, and 7.04 ppm tilmicosin in liver, muscle and kidney tissue, respectively; and 1.15 ppm and 0.83 ppm sulfadimethoxine in liver and muscle tissue, respectively. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in edible tissue of cattle (21 CFR Section 556.640). See above paragraph for 21 CFR tolerances for penicillin and tilmicosin. The presence of these drugs in the edible tissue from this animal causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our investigator also found that you hold animals under conditions which are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack

an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residue of drugs from edible tissue. Foods from animals held under such conditions are adulterated within the meaning of Section 402(a)(4) of the Act.

You are adulterating the drugs penicillin and sulfadimethoxine within the meaning of Section 501(a)(5) of the Act when you fail to use the drugs in conformance with their approved labeling. Your use of these drugs in cows without following labeled withdrawal periods cause the drugs to be unsafe to use.

This letter may not list all the deviations at your farm. As a producer of animals offered for use as food, you are responsible for assuring that your overall production and the foods you distribute are in compliance with the law.

It is not necessary for you to personally ship adulterated animals in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of animals that were sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen(15) working days of receipt of this letter of the steps you have taken to bring your farm into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete corrections within 15 working days, we expect you to explain the reason for the delay and state when any remaining deviations will be corrected. Please include copies of any documentation demonstrating that corrections have been made.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Howard E. Lewis
Acting Director, New Orleans District

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Enclosures:
21 CFR 556.510
21 CFR 556.735
21 CFR 556.640
21 CFR 558.618